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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,952	05/04/2005	Toshikazu Koyama	1349.45033X00	9610

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ARLINGTON, VA 22209-3873

EXAMINER
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UNDERDAHL, THANE E

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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07/10/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

officeaction@antonelli.com  
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## Office Action Summary

**Application No.**

10/533,952

**Applicant(s)**

KOYAMA ET AL.

**Examiner**

Thane Underdahl

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08).<br>Paper No(s)/Mail Date <u>5/4/05</u> . | 6) <input type="checkbox"/> Other: _____  |

DETAILED ACTION

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 contains the phrase "amylase protease". This term is indefinite because the Examiner is not familiar with this protein. In the interest of compact prosecution, the Examiner will take this as a typo and the phrase will read "amylase \_protease". However, clarification is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Shibahara et al. (U.S. Patent # 5753223) with support from Answers.com.

These claims are drawn to a granular composition that has two parts: a core made of saccharides and a coating that is made of hardened oil and a bioactive ingredient.

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The core comprises granulated sugar or lactose. The hardened oil is further limited to palm oil. The bioactive ingredient is limited to an enzyme from the group consisting of a cellulase, amylase, protease, and lipase. Claims 7-9 are Product by Process claims that limit the origin of the enzymes. Product by Process claims are not limited by the origin of the enzymes, only the structure implied by the enzymes to the composition (M.P.E.P. § 2113). As such, these methods of preparation do not impart a functional relationship to the granular composition and are not further limiting and unless the applicant provides evidence to the contrary that the origin of the enzyme is indeed a necessary limitation, the claim will read on any of the selected enzymes regardless of origin.

Shibahara et al. teach a granular composition comprising a core material coated with a hardened oil and bioactive ingredient such as enzyme or pancreatin (Shibahara, Abstract and Example 8). The core of the material are granulated sugars such as sucrose, glucose and starch (Shibahara, col 3, lines 30-35). The hardened oil can be palm oil (Shibahara, col 4, lines 1-5). The enzymes in the coating can be lipase (Shibahara, col 4, lines 10-15) or a mixture of enzymes (Shibahara, col 4, 20-25) such as pancreatin (Shibahara, Example 8) which inherently contains, amylase, lipase and the protease trypsin as supported by Answers.com (Definition: Pancreatin).

Therefore the reference anticipates claims 1-5 and 7-9.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibahara et al. (U.S. Patent # 5753223) as applied to claims 1-5 and 7-9 above and further view of arguments below.

The description and rejection of claims 1-5 and 7-9 are listed in the 35 U.S.C § 102(b) rejection above. Claim 12 limits that the bioactive agent is 0.1 to 15% by weight in the coating.

While Shibahara et al. teaches that bioactive ingredients such as enzymes are indeed in the coating and they state concerning the concentration of the coating that "The amount of enzyme used is not limited" (Shibahara, col 4, lines 20-25), Shibahara et al. does not specifically teach the limitations of claim 12. However, M.P.E.P. § 2144.05 II states:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the amounts listed in claim 12 for the concentrations of bioactive ingredients, it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the concentrations are result effective variables whose ratio and concentration are a matter of routine optimization.

Therefore the references listed above renders obvious claims 1-5, 7-9 and 12.

Claims 1-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibahara et al. as applied to claims 1-5, 7-9 and 12 above, and further in view of Nishimura et al. (U.S. Patent # 5571527).

The description and rejection of claims 1-5, 7-9 and 12 are listed in the 35 U.S.C § 103(a) rejection above. Claim 6 limits that the enzyme is cellulase. While Shibahara et al. does explicitly teach the addition of cellulase to their coating they do teach that their enzymes in the coating layer are meant to "enhance(s) the effects of the digestive enzymes secreted by the ruminant ...as well as dissolution of the biologically active substance" (Shibahara et al., col 5, lines 25-30). Furthermore the granulated saccharide core of Shibahara et al. contains components such as starch, glucose, sucrose (Shibahara, col 3, lines 30-35) and carboxymethylcellulose (Shibahara Example 6). Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Nishimura et al. who teach an another composition that contains a coating. Nishimura et al. teach the addition of cellulase as well as lipase and amylase to their composition (Nishimura, col 6, lines 1-5) to assist in digestion (Nishimura et al. col 1, lines 30-35). One of ordinary skill in the art would recognize that ruminant animals have cellulase in their digestive tracts to process high cellulose foods such as grass. It would have been obvious to someone skilled in the art to add cellulase to the coating in the invention of Shibahara et al. Since Shibahara et al. provides motivation by stating that the enzymes in the coating layer are

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meant to (A) "enhance(s) the effects of the digestive enzymes secreted by the ruminant" as well as assist in the (B) "dissolution of the biologically active substance" (Shibahara et al., col 5, lines 25-30) it would have been obvious to someone skilled in the art that the addition of cellulase accomplishes both of these goals. First in object (A) adding more cellulase to the digestive track will enhance the digestibility of high cellulose food in the ruminant. Also (B) will be achieved since the formulations of Shibahara et al. include cellulose derivatives that would be broken down by the cellulase and provide added nutrient to the ruminant animal. The reasonable expectation of success is provided by Nishimura et al. who teach a composition for ruminants where cellulase is added to enhance digestion. Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 1-9 and 12 are not allowable.

Claims 1-5, 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibahara et al. as applied to claims 1-5, 7-9 and 12 above, and further in view of Ludwig et al. (U.S. Patent # 4293539).

The description and rejection of claims 1-5, 7-9 and 12 are listed in the 35 U.S.C § 103(a) rejection above. Claims 10 and 11 are limit that the bioactive ingredient in the coating is the antibiotic, colistin.

Shibahara et al. teach the addition of antibiotics to their composition for ruminant animals (Shibahara, col 3, lines 40-45) but does not teach that they are in the coating. Regardless this would be obvious to one of ordinary skill in the art by the time the

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invention was made in view of the teachings of Ludwig et al. They teach a composition that contains many of the similar coating ingredients such as beeswax, gelatin, cocoa butter and alginic acid with similar properties (Ludwig, col 5, lines 48-55) of those of Shibahara et al. including vegetable and animal oils that also harden or gel. One of ordinary skill in the art would recognize that both compositions could be used to coat the cores of the invention Shibahara et al. since these coating components do have similar properties to gel. The composition of Ludwig et al. is also to act as a supplement to treat ruminant animals. In particular Ludwig et al. teach that their composition includes the antibiotic colistin (Ludwig et al. col 4, lines 35-40). It would have been obvious to someone skilled in the art to combine the teachings of Shibahara et al. with those of Ludwig et al. and add the antibiotic colistin to the hardened oil coating formulation of Shibahara et al. The motivation comes from Ludwig et al. who successfully treats ruminants with antibiotics using supplement polymer formulations that use vegetable oils and gelatin that have similar properties such as gelling as those used by Shibahara et al. The reasonable expectation of success comes from Ludwig et al. who successfully treat the ruminants with their gel-like formulations.

Therefore the references listed above renders obvious claims 1-5, 7-12.

In summary no claims, as written, are allowed for this application.

**In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for**



interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

#### CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

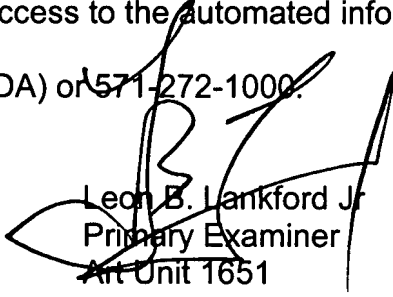
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